

112. The seed of claim 24, wherein the *ADC* polynucleotide encodes a polypeptide comprising an AP2 domain which is at least 60% identical to SEQ ID NO: 4 or SEQ ID NO: 5.

113. The transgenic plant of claim 35, wherein the *ADC* polynucleotide encodes a polypeptide comprising an AP2 domain which is at least 60% identical to SEQ ID NO: 4 or SEQ ID NO: 5.

114. The method of claim 45, wherein the *ADC* polynucleotide encodes a polypeptide comprising an AP2 domain which is at least 60% identical to SEQ ID NO: 4 or SEQ ID NO: 5.--

#### REMARKS

Claims 1-37, 40-41, and 45-114 are currently pending. Claims 1-44 currently stand rejected for alleged nonstatutory obviousness-type double patenting. Claims 1-44 are also rejected under 35 U.S.C. § 112, second paragraph for alleged indefiniteness as well as under 35 U.S.C. § 112, paragraph 1 for lack of enablement. Claims 35, 36, 38, 39, 40, 41, and 43 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Jofuku *et al.*

New claims 45-114 have been added to claim more particularly the subject matter of the invention. New claim 45 recites a method of modulating seed oil content in a plant, the method comprising: 1) providing a first plant comprising a recombinant expression cassette containing an *ADC* nucleic acid linked to a plant promoter, which *ADC* nucleic acid encodes a portion of an AP2 domain which is at least 35% identical to a polypeptide sequence comprising SEQ ID NO:4 or SEQ ID NO:5 and which *ADC* nucleic acid encodes a polypeptide that affects seed mass or oil content when expressed in seed or floral tissue; 2) selfing the first plant or crossing the first plant with a second plant, thereby producing a plurality of seeds; and 3) selecting seed with altered oil content. Claim 45 is supported in the Specification on, *e.g.*, page 44, lines 6-14.

New claims 46-110 are directed to particular sequences recited in Markush groups in claims 5, 15, 26, 36 and 41. Claims 111-114 are directed to ADC nucleic acids which encode a polypeptide having an AP2 domain which is at least 60% identical to SEQ ID NO:4 or SEQ ID NO:5. These claims are based on the amendments made in response to the 35 USC § 112, second paragraph, rejection, discussed below. Support for the particular percent identity recited in claims 111-114 is found on page 7, line 20. No new matter is added by these amendments.

The Specification has been amended to correctly identify the above-referenced application as a continuation-in-part rather than as a continuation.

**Obviousness-type Double Patenting Rejection**

The Examiner rejected claims 1-44 under the judicially created doctrine of obviousness-type double patenting in light of copending applications 08/700,152 and 08/912,272. If necessary, an appropriate terminal disclaimer will be filed with the United States Patent Office when it is indicated that the claims would otherwise be allowable.

**35 U.S.C. 112, Second Paragraph Rejections**

**Indefiniteness Rejection**

Claims 1-44 stand rejected under 35 U.S.C. § 112, second paragraph for alleged indefiniteness. The Examiner alleges that the claims are so broad as to encompass “virtually anything affecting seed properties.” According to the rejection, “ADC nucleic acid,” as used in claims 1-44, was allegedly not defined clearly in the specification. As noted by the Examiner, an ADC nucleic acid is defined as a polynucleotide which, encodes a polypeptide containing an AP2 domain and which modulates seed properties in seed produced by the plant. The Examiner alleges that an AP2 domain is defined only by reference to the Jofuku *et al.*, reference. In fact, exemplary AP2 domains are provided in Figure 1A of the specification.

Applicants respectfully traverse. The claims as filed would be clear to one of ordinary skill in the art. In conjunction with the specification, one of ordinary skill in the art would recognize that the AP2 sequence can be modified without substantially altering the sequence’s ability to modulate seed growth. One of ordinary skill in the art, however, would not recognize that any sequence that modulates seed properties, no matter how divergent from

an AP2 domain, falls within the above-described definition of an “ADC nucleic acid”.

Applicants submit that for a sequence to fall within the above-described definition of an “ADC nucleic acid,” that sequence must be substantially identical to an AP2 domain as set forth on page 6, line 5 of the specification. “Substantial identity” is defined, *inter alia*, on page 7 of the specification and includes a requirement that the subject polypeptide be at least 35% identical to the reference sequences. (see page 7, lines 19-21).

Applicants note that in the Final Office Action of the parent application, similar claims were pending and rejected for allegedly being indefinite (see Office Action mailed April 29, 1998, in USSN 08/700,152). In that Action, the Examiner alleged that the specification, does not provide sufficient teaching to allow one of skill to determine sequence identity as recited in the claims. Applicants are preparing a declaration explaining why the disclosure of the present application is sufficient for one of skill to use a commonly available sequence comparison program (BLAST) to compare sequences, as set forth in the specification at page 7, line 15.

To further clarify the scope of the present invention, the claims have been amended to expressly recite, as noted above, the definition of an ADC nucleic acid that would be understood by one skilled in the art in light of the Specification. The amended claims recite an ADC nucleic acid encodes a portion of an AP2 domain that is at least 35% identical to either of two AP2 domains disclosed in the specification (SEQ ID NO:4 or SEQ ID NO:5). No new matter is added by this amendment. Applicants reserve the right to prosecute the original claims in current or future patent applications. Applicants submit that all of the claims as amended clearly describe the invention and therefore are not indefinite.

*Incorporation by Reference rejection*

The rejection stated that claims 5, 15, 26, 36, and 41 were allegedly unclear because they refer to Genbank accession numbers rather than to sequences set forth in the specification. According to the rejection, the above-identified claims contained an alleged improper incorporation by reference and, furthermore, reference to Genbank accession numbers is allegedly improper because they are not irrevocably fixed.

To clarify the disclosure, sequence identification numbers were added to the Specification. As the sequence identification numbers represent identical material to the

Genbank accession numbers as originally filed, no new matter was added by this amendment. Amended claims 5, 15, 26, 36, and 41 refer to sequences identified by sequence identification numbers. Furthermore, an appropriate sequence identification number listing is included as part of this amendment. Therefore, the claims do not utilize an improper incorporation by reference.

In response to the Examiner's concern about the possibility that Genbank sequences can change over time, Applicants' representatives have confirmed via correspondence with the Genbank User Services at the National Institute of Health that Genbank accession numbers do not change (see email correspondence attached as Appendix I). Any changes to a sequence are noted in the "comment" field of the Genbank record and can be accessed via the internet (see *e.g.*, <http://www.ncbi.nlm.nih.gov/htbin-post/Entrez/girevhist>). One of ordinary skill in the art would therefore know whether particular sequences have changed as well as how they were changed. In the present case, the Genbank accessions have not changed since the sequences were submitted. Evidence in the form of printouts of the Genbank records for each of the sequences claimed here can be provided, if requested by the Examiner. Applicants, therefore submit that no declaration is necessary to establish that the material as amended with sequence identification numbers is the same as was incorporated by reference with Genbank accession numbers.

*Rejection of Claim 44*

The Examiner rejected claim 44 because it was not clear. Claim 44 is deleted by this amendment and the rejection is therefore moot.

**35 U.S.C. § 112, First Paragraph Rejection**

*Undue Experimentation Rejection*

The rejection questioned whether the claimed nucleotide sequences can influence seed properties (see page 6 of the rejection). The Examiner alleges that undue experimentation would be required to practice the full scope of the invention. Applicants respectfully traverse.

In assessing enablement, a specification that has claims that correspond in scope to the teaching in the specification must be taken as enabling, unless there is reason to doubt the objective truth of the assertions of enablement. It is incumbent upon the Examiner to

explain why the truth or accuracy of the statements in the application should be doubted. These assertions must be backed up with acceptable evidence or reasoning. *In re Marzocchi*, 169 USPQ 367 (CCPA 1971). As explained below, the Examiner has failed to meet her initial burden of providing sufficient evidence or reasoning to support this rejection.

The invention as recited in the original claims does not require undue experimentation. The claims recite methods and compositions that involve plants comprising an *ADC* nucleic acid where the plants have altered mass or oil content. Applicants submit that the specification provides simple assays by which one of skill could readily determine whether a particular nucleic acid functions in the manner claimed here. For instance, it would be a simple matter for one of ordinary skill in the art to insert a test nucleic acid into a plant, measure seed mass (see, *e.g.*, Specification page 26, lines 28-31) or seed oil content (see, *e.g.*, Specification page 46 and Patak *et al. Curr. Sci.* 67, 470-472 (1994)) of the resulting transgenic plant, and therefore determine whether the insert is a *ADC* nucleic acid of the invention.

It is well established that enablement is not precluded by the necessity of some experimentation, such as routine screening. As the Federal Circuit has stated, "the key word is 'undue', not 'experimentation'" in determining whether pending claims are enabled. *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Furthermore, it is irrelevant that all possible embodiments of the invention may not result in plants with altered seed mass or oil content. Claims that read on inoperative embodiments are not necessarily invalid for lack of enablement unless one of skill in the art would have to experiment unduly to practice the invention. See *Atlas Powder Co. v. E.I. DuPont De Nemours & Co.*, 750 F.2d 1569 (Fed. Cir. 1984). In light of these holdings and the above discussion, the Examiner must explain why one of ordinary skill in the art could not identify *ADC* nucleic acids that result in altered seed mass or oil content when the sequence is inserted into plants using the present disclosure.

Claims 1, 24, and 42 are amended to clarify what seed properties are influenced by the sequences of the invention. Amended claims 1, 24 and 42 recite that the polypeptide encoded by the *ADC* nucleic acid modulates seed mass or oil content. No new matter was added by this amendment. As discussed above, in light of the original disclosure, one of skill in the art could easily identify *ADC* nucleic acids that result in altered seed mass or oil content as

claimed in the amended claims. Therefore, Applicants submit that the amended claims do not require undue experimentation to practice the full scope of the invention, and thus the claims are in condition for allowance.

**35 U.S.C. 102(b) Rejection**

Claims 35, 36, 38, 39, 40, 41 and 43 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Jofuku *et al* (1994). In particular, the Examiner points to language in this reference generally describing the insertion of antisense constructs comprising the AP2 gene disclosed there (SEQ ID NO:3 of the present application) in *Arabidopsis*. To facilitate prosecution, claims 38, 39, and 43 are deleted by this amendment. In addition, claims 24, 35, and 40 have been amended to specifically exclude the disclosure of the Jofuku *et al*. reference.

In particular, claim 24 has been amended to exclude seed derived from *Arabidopsis*, as described in Jofuku *et al*. Similarly, claim 35 is now directed to transgenic plants that are not *Arabidopsis*. Finally, claim 40 has been amended to exclude nucleic acid molecules comprising SEQ ID NO: 3.


Applicants respectfully submit that the subject matter of the amended claims neither disclosed nor suggested by Jofuku *et al*. Applicants have made the above amendments only to expedite prosecution and specifically reserve the right to pursue the original claims in one or more subsequent applications.

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CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at 415-273-7554.

Respectfully submitted,

  
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